

REMARKS

The office action of December 14, 2006 has been reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested.

Claims 1-38 are pending in the application. By this amendment, new claims 33-38 have been added. Support for new claims 33-38 can be found in the application as originally filed. Reconsideration and allowance of the instant application are respectfully requested.

Allowable subject matter

Applicants thank the examiner for indicating that claims 30-32 are allowable.

Outstanding rejections

Claims 1-24 and 27-29 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. patent no. 4,867,176 to Lash (Lash) in view of U.S. patent no. 5,137,032 to Harmon (Harmon). Claims 25-26 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lash in view of Harmon and further in view of U.S. patent no. 6,170,484 to Feng (Feng). Reconsideration and allowance of these claims are respectfully requested.

Claims 1-22

The specification discloses example female condoms that can provide a high degree of stability during use for a variety of different sizes of women. *See e.g.*, page 11, paragraph 47. These female condoms have cling elements disposed at an intermediate portion of the pouch for anchoring the pouch in or slightly beyond the user's introitus. For instance, for the example female condom shown in Figure 1, "cling elements 15 are disposed at an intermediate portion of pouch 10 along its outer surface." Page 8, paragraph 39, lines 1 and 2. The cling elements 15 are "placed at gate length g from outer ring 17 for anchoring pouch 10 in or slightly beyond the user's introitus." *Id.* at paragraph 40, line 2. Similarly, the examples shown in Figures 3 and 5 illustrate the inventive subject matter of placing cling elements at a gate length g from the outer

ring/condom opening for anchoring the pouch in or slightly beyond the user's introitus (vaginal opening) to provide a high degree of stability for different sizes of women.

Independent claim 1 recites the inventive subject matter of one or more hydrophilic cling elements attached to the outer surface of the pouch that are disposed between the open end and the closed end of the pouch, which are adapted to cling lightly to walls of a vagina proximate a transition zone between the vagina's introitus and its rugated internal vaginal tissue for anchoring the pouch in or slightly beyond the introitus.

Similarly, independent claim 18 recites the subject matter of a female condom having a cling mechanism attached to the outer surface of the pouch, which, upon insertion in a user's vagina, comes into contact with vaginal walls proximate a transition zone between the vagina's introitus and its rugated internal vaginal tissue.

At least this subject matter of independent claims 1 and 18 is not taught or suggested by the cited prior art.

The Office Action correctly notes that Lash "fails to disclose hydrophilic cling elements attached to the outer surface of the female condom and adapted to anchor said pouch in or slightly beyond the vagina's introitus." Office Action, page 3, lines 4-6. In addition, the Office Action asserts that Harmon discloses "friction-imparting agent (20) [that] clings to the vaginal walls in order to stabilize the condom within the vagina." *Id.* at lines 14-15. Accurately, the Office Action does not assert that Harmon's friction-imparting agent (20) clings to or comes into contact with the vaginal walls proximate a transition zone between the vagina's introitus and its rugated internal vaginal tissue. Neither Lash nor Harmon teaches this inventive subject matter, nor does the Office Action assert that they do. Harmon actually teaches the opposite.

Instead, Harmon teaches making the length of the condom 2 to 3 inches longer than a regular condom "so that folds can form during use just distally of the fixed or tight portion, i.e., portion 24 ... allowing the closed end 14 to slide off and onto the penis." Col. 4, lines 15-20. Thus, like other prior art female condoms that are susceptible to shifting or twisting (*see e.g.*, Background of the present application, paragraphs 6 to 8), Harmon actually teaches anchoring the condom at its distal end. Further, Harmon teaches away from anchoring the condom in the region proximate the transition zone between the vagina's introitus and its rugated internal vaginal tissue.

More particularly, Harmon teaches placing its friction imparting agent “in several spaced apart patches or bands 20 that together cover the distal end of the condom, i.e., the portion adjacent the closed end 14,” which would not cling or come into contact with the vagina’s introitus (opening) or the transition zone between the introitus and the rugated internal vaginal tissue during use.

For at least these reasons, Applicants respectfully submit that independent claims 1 and 18 are patentable over Lash in view of Harmon, as well as claims 2-17 and 19-22 depending therefrom.

Claims 23-29

The specification discloses example female condoms that can eliminate “the need for an external insertion aid (e.g., tube-type inserter similar to that used for tampons) – foam cap 20 takes the place of the inserter tube.” Specification, paragraph 45, lines 2-4. The example foam cap 20 shown in Figures 1 and 2 is generally softer, more compact and easier to handle than a plastic inserter of the prior art, such as the applicator 26 of Lash. *Id.* at lines 6-8. “As also shown in Fig. 1, the distal portion of the condom is preferably packaged in a collapsed, compressed state ... The collapsed and compressed portion of pouch 10 is held together by cap 20, which aids insertion.” *Id.* at page 11, paragraph 48, lines 1-5.

Similar to the example condom of Figure 1, independent claim 23 recites the inventive subject matter of a packaged female condom comprising, among other features,

an inserter coupled to said distal end of the pouch, said inserter retaining a distal portion of said pouch and said cling mechanism in a collapsed form;

wherein, upon insertion into a user’s vagina, said cling mechanism deploys from said inserter and comes into contact with vaginal walls for lightly clinging to said vaginal walls.

Emphasis added. At least this inventive subject matter of independent claim 23 is not taught or suggested by the cited prior art.

The Office Action refers to the thickened hemispherical portion 37 shown in Figure 4 of Lash and asserts that it is an inserter for condom 36, which can be inserted using an applicator 26. The Office Action also refers to cup-like receptacle 68 shown in Figure 16 as a cap-like receptacle or inserter. However, neither the thickened hemispherical portion 37 nor the cup-like receptacle 68

of Lash retains a distal portion of the pouch and the cling mechanism in a collapsed form, and a cling mechanism does not deploy from either of these features upon insertion into the user's vagina.

Lash simply does not disclose or suggest a packaged female condom having the inventive inserter recited in independent claim 23 such that it retains both a distal portion of the pouch and cling elements in collapsed form and from which the cling elements deploy during insertion. No portion of the condom of Lash is collapsed within the thickened hemispherical portion 37 and nothing deploys from it when inserted. Further, cup-like receptacle 68 is simply a disposable package for the condom, which is not inserted into the user's vagina. Clearly, Lash fails to teach or suggest this inventive subject matter of independent claim 23. Neither Harmon nor Feng overcome these deficiencies of Lash, nor were they relied upon to do so.

For at least these reasons, Applicants respectfully submit that independent claim 23 and claims 24-29 depending therefrom are patentable over Lash in view of Harmon, either alone or further in view of Feng.

Claims 3, 7, 19, 24

In addition to the reasons discussed above, Applicants respectfully submit that dependent claims 3, 7, 19 and 24 are allowable over the cited prior for at least the following reasons. Dependent claims 3, 7, 19 and 24 each recite subject matter of a hydrophilic foam cling element or a polyurethane hydrophilic foam segment, which subject matter is not taught or suggested by the cited prior art.

The Office Action asserts that Harmon teaches the use of polyvinyl alcohol foam. However, Harmon fails to teach or suggest the use of any types of foams, much less the recited hydrophilic foam cling elements or polyurethane hydrophilic foam segment. Instead, Harmon discloses the use of hydrocolloid gum in a dry state as a "powder composed of minute particles 30, some of which are exposed at the surface and some of which are embedded in a matrix 32." Col. 4, lines 24-27. The matrix is formed of rubbery substances or an aqueous solution within which the hydrophilic foam is mixed and which can be applied to the condom via dipping, spraying, brushing, etc. *Id.* at lines 45-62. Additional powdered gum is preferably added to the tacky outer surface of the matrix. *Id.* at lines 63-64. Clearly, the hydrophilic matrix and

powdered gum disclosure of Harmon fails to teach hydrophilic foam cling elements or polyurethane hydrophilic foam segment as recited in claims 3, 7, 19 and 24.

For these additional reasons, Applicants respectfully submit that claims 3, 7, 19 and 24 are allowable over the cited prior art.

Claims 5, 6 and 21

In addition to the reasons discussed above, Applicants respectfully submit that dependent claims 5, 6 and 21 are allowable over the cited prior for at least the following reasons. Dependent claims 5, 6 and 21 each recite the subject matter of a hydrophilic foam cling element that defines a generally elliptical shape, a generally triangular shape and/or a generally circular shape, which subject matter is not taught or suggested by the cited prior art.

The Office Action asserts that Harmon discloses, “the friction-imparting agent (20) is defined generally by an elliptical shape.” Office Action, page 3, line 11. The Office Action refers to Harmon, col. 4, line 39, to support this position. However, there is no disclosure of an elliptical, triangular or circular shape for the friction-imparting agent in Harmon at the referenced location or elsewhere in the reference. If the Patent Office maintains this rejection, Applicants respectfully request that it identify these teachings within the cited prior art.

For these additional reasons, Applicants respectfully submit that claims 5, 6 and 21 are allowable over the cited prior art.

Claim 8

In addition to the reasons discussed above, Applicants respectfully submit that dependent claim 8 is further allowable over the cited prior for at least the following reason. Dependent claim 8 recites the inventive subject matter of at least one hydrophilic cling element having a total surface area of approximately 0.75 square inches, which is not taught or suggested by the cited prior art.

The Office Action takes the position that Applicants have not provided a particular advantage or solved a stated problem with respect to the subject matter of claim 8, or that it serves a purpose different than that of any hydrophilic frictional element connected to a condom. However, as noted in the specification at least at page 11, paragraph 46, the cling elements

provide a surface treatment or mechanism that provides a cling or light adhesion against the vaginal mucosa. “The cling force should exceed the pull-out forces created by withdrawal of the penis during sex in order for the condom to remain stable and maintain comfort, sensation, safety and effectiveness.” *Id.* at lines 8-10. These advantages and purposes are accomplished via various female condom configurations disclosed in the specification, including various sizes, shapes, surface areas, arrangements and types of cling elements. As noted in the specification on page 9, paragraph 41, lines 14-17, one preferred arrangement of cling elements that accomplishes these purposes has an average total surface area of 0.75 in². Accordingly, Applicants respectfully submit that the specification discusses advantages for a condom configuration that includes the inventive subject matter of claim 8.

For these additional reasons, Applicants respectfully submit that claim 8 is allowable over the cited prior art.

Claims 25-26

In addition to the reasons discussed above, Applicants respectfully submit that dependent claims 25 and 26 are allowable over the cited prior art for at least the following reasons. Dependent claims 25 and 26 each recite the subject matter of pleats formed in the distal portion of the pouch of female condom package, which subject matter is not taught or suggested by the cited prior art.

The Office Action asserts that Feng “teaches a plurality of longitudinal and horizontal pleats (fig. 6) on a female condom (101).” Office Action, page 4, lines 16-17. However, Feng fails to disclose a female condom at all, much less pleats in a female condom package. Feng actually discloses a semi-rigid contraceptive device that is similar to a diaphragm, fails to conform to vaginal tissue, and is completely retained within the vaginal canal. Instead of having pleats, “The outer wall 119 of the [Feng] device 101 has surface protrusions 121, which according to one embodiment form a double-layer wavy ring-shaped pattern.” Col. 3, lines 58-61. The rigid surface protrusions 121 of Feng fail to teach or suggest the inventive subject matter of pleats formed in the distal portion of a pouch of a female condom package as recited in claims 25 and 26.

For this additional reason, Applicants respectfully submit that claims 25 and 26 are allowable over the cited prior art.

Conclusion

Based on the foregoing, Applicants respectfully submit that the application is in condition for allowance and a Notice to that effect is earnestly solicited. Should the Examiner believe that anything further is desirable in order to place the application in even better form for allowance, the Examiner is respectfully urged to contact Applicants' undersigned representative at the below-listed number.

Respectfully submitted,

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